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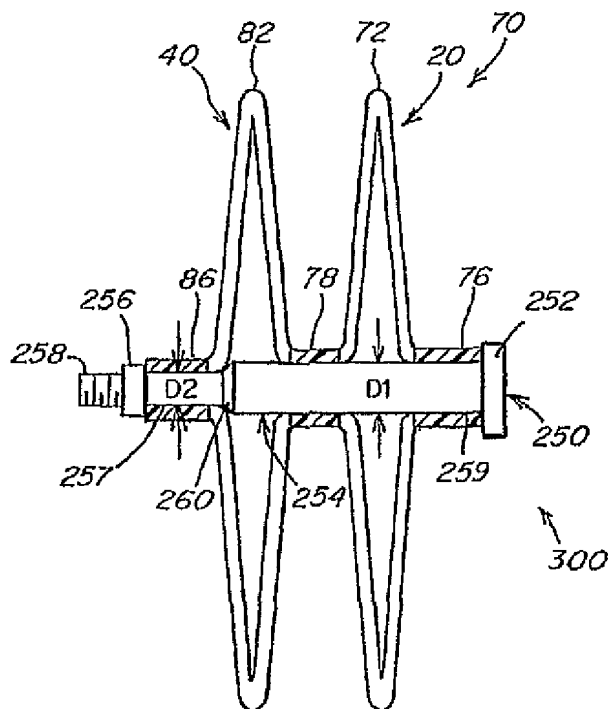
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(54) Title: CATCH MEMBER FOR PFO OCCLUDER



(57) Abstract: Delivery (and recovery) devices and techniques for delivering an implant into a desired location within the body and catch systems for such implants. The devices and techniques relate particularly to, but are not limited to, a patent foramen ovale (PFO) occluder made from a polymer tube. A catch system maintains an occluder in a deployed configuration by holding it in a reduced axial length position. Some embodiments have a compressible tip. Some embodiments have temporary catching mechanisms.



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Catch Member for PFO Occluder

REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Provisional Patent Application Ser. No. 60/663,289, filed March 18, 2005, the disclosure of which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

[0002] This disclosure relates generally to an occlusion device for the closure of physical anomalies, such as an atrial septal defect, a patent foramen ovale (PFO), and other septal and vascular defects; the disclosure relates particularly catch systems and catch members for such a device.

BACKGROUND

[0003] A patent foramen ovale (PFO), illustrated in FIG. 1, is a persistent, one-way; usually flap-like opening in the wall between the right atrium 11 and left atrium 13 of the heart 10. Because left atrial (LA) pressure is normally higher than right atrial (RA) pressure, the flap usually stays closed. Under certain conditions, however, right atrial pressure can exceed left atrial pressure, creating the possibility that blood could pass from the right atrium 11 to the left atrium 13 and blood clots could enter the systemic circulation. It is desirable that this circumstance be eliminated.

[0004] The foramen ovale serves a desired purpose when a fetus is gestating. Because blood is oxygenated through the umbilical cord, and not through the developing lungs, the circulatory system of the fetal heart allows the blood to flow through the foramen ovale as a physiologic conduit for right-to-left shunting. After birth, with the establishment of pulmonary circulation, the increased left atrial blood flow and pressure results in functional closure of the foramen ovale. This functional closure is subsequently followed by anatomical closure of the two over-lapping layers of tissue: septum primum 14 and septum secundum 16. However, a PFO has been shown to persist in a number of adults.

[0005] The presence of a PFO is generally considered to have no therapeutic consequence in otherwise healthy adults. Paradoxical embolism via a PFO is considered

in the diagnosis for patients who have suffered a stroke or transient ischemic attack (TIA) in the presence of a PFO and without another identified cause of ischemic stroke. While there is currently no definitive proof of a cause-effect relationship, many studies have confirmed a strong association between the presence of a PFO and the risk for paradoxical embolism or stroke. In addition, there is significant evidence that patients with a PFO who have had a cerebral vascular event are at increased risk for future, recurrent cerebrovascular events.

[0006] Accordingly, patients at such an increased risk are considered for prophylactic medical therapy to reduce the risk of a recurrent embolic event. These patients are commonly treated with oral anticoagulants, which potentially have adverse side effects, such as hemorrhaging, hematoma, and interactions with a variety of other drugs. The use of these drugs can alter a person's recovery and necessitate adjustments in a person's daily living pattern.

[0007] In certain cases, such as when anticoagulation is contraindicated, surgery may be necessary or desirable to close a PFO. The surgery would typically include suturing a PFO closed by attaching septum secundum to septum primum. This sutured attachment can be accomplished using either an interrupted or a continuous stitch and is a common way a surgeon shuts a PFO under direct visualization.

[0008] Umbrella devices and a variety of other similar mechanical closure devices, developed initially for percutaneous closure of atrial septal defects (ASDs), have been used in some instances to close PFOs. These devices potentially allow patients to avoid the side effects often associated with anticoagulation therapies and the risks of invasive surgery. However, umbrella devices and the like that are designed for ASDs are not optimally suited for use as PFO closure devices.

[0009] Currently available septal closure devices present drawbacks, including technically complex implantation procedures. Additionally, there are significant complications due to thrombus, fractures of the components, conduction system disturbances, perforations of heart tissue, and residual leaks. Many devices have high septal profile and include large masses of foreign material, which may lead to unfavorable body adaptation of a device. Given that ASD devices are designed to occlude holes, many lack anatomic conformability to the flap-like anatomy of PFOs. Thus, when inserting an ASD device to close a PFO, the narrow opening and the thin flap may form impediments to proper deployment. Even if an occlusive seal is formed, the device may

be deployed in the heart on an angle, leaving some components insecurely seated against the septum and, thereby, risking thrombus formation due to hemodynamic disturbances. Finally, some septal closure devices are complex to manufacture, which may result in inconsistent product performance.

[0010] The techniques disclosed herein are designed to address these and other deficiencies of prior art septal closure devices and techniques for delivering and retrieving such devices.

SUMMARY

[0011] This specification discloses catch systems and techniques for catching an implant in its deployed configuration. These devices and techniques relate particularly to, but are not limited to, a septal occluder made from a polymer tube. These devices and techniques, in addition to use with septal occluders, could be applied to other medical devices, such as other expandable devices constructed from an underlying tubular structure.

[0012] A catch system is disclosed that reduces and maintains the reduced axial length of the device in its deployed configuration. Also, varied constructions could be used to maintain the axial dimension of the device. In some embodiments, a catch member secures the ends of the occluder in a compressed position. Preferably it secures both sides of the device in the deployed position with a single catch member. In one aspect, the catch member includes a ridge to provide a friction fit to catch the deployed occluder. In another aspect, the catch member includes a compressible tip. The tip can be compressed to reduce the profile of the compressible portion, especially to facilitate delivery and deployment. When the occluder is released from the delivery system and during the deployment process, the compressible tip expands such that the friction fit provided by the ridge, or other catch mechanism, is engaged. In another aspect, the catch member includes a temporary catching mechanism to temporarily secure the occluder in a compressed position before the catch mechanism is fully engaged. In one embodiment, a cylindrical portion of the catch member along which the occluder slides includes a first

portion having a first diameter and a second portion having a second diameter. A portion of the occluder having an inner diameter smaller than the larger diameter removably catches on the larger diameter to temporarily secure the occluder in a compressed position before the catch mechanism is fully engaged.

[0013] These and other aspects and embodiments of the disclosure are illustrated and described below.

BRIEF DESCRIPTION OF THE DRAWINGS

In the Drawings:

- [0014] FIG. 1 is a schematic representation of a human heart including various septal defects;
- [0015] FIG. 2 illustrates a deployed occluder according to an aspect of the disclosure;
- [0016] FIG. 3 illustrates introduction of the occluder in a human heart using a delivery system in accordance with an aspect of the disclosure;
- [0017] FIG. 4 illustrates a detail view of a delivery catheter in a heart with its tip approaching a patent foramen ovale between the left atrium and right atrium;
- [0018] FIGS. 5-8 illustrate an occluder according to the present invention in a sequence between a reduced profile delivery configuration (FIG. 5) and an expanded profile deployed configuration (FIG. 8);
- [0019] FIG. 9A is a side view of a catch member with a compressible tip in accordance with one aspect of the disclosure;
- [0020] FIG. 9B is a side view of a catch member with a compressible tip in accordance with one aspect of the disclosure, in a delivery configuration;
- [0021] FIG. 9C is a perspective view of a catch member with a compressible tip in accordance with one aspect of the disclosure;
- [0022] FIG. 10A is a side view of a catch member in accordance with one aspect of the disclosure;
- [0023] FIG. 10B is a side view of a catch member and an occluder in accordance with one aspect of the disclosure;
- [0024] FIG. 10C is a close-up view of a portion of a catch member and an occluder in accordance with one aspect of the disclosure; and
- [0025] FIG. 10D is a close-up view of a portion of a catch member and an occluder in accordance with one aspect of the disclosure.

DETAILED DESCRIPTION

[0026] The present disclosure provides devices, delivery/retrieval systems and techniques for delivering such devices intended to occlude an aperture within body tissue. In particular and as described in detail below, the described occluder may be used for closing an ASD or PFO in the atrial septum of a heart. Although the embodiments are described with reference to an ASD or PFO, one skilled in the art will recognize that the device and methods of the present invention may be used to treat other anatomical conditions. As such, the invention should not be considered limited in applicability to any particular anatomical condition. In addition, the systems and methods for delivery and retrieval, and for catching a device in a deployed state, which are aspects of the present invention may also be used in connection with other types of devices besides an occluder, in particular, devices having tubular profiles.

[0027] FIG. 1 illustrates a human heart 10, having a right atrium 11 and a left atrium 13 and including various anatomical apertures 18a and 18b. The atrial septum 12 includes septum primum 14 and septum secundum 16. The anatomy of the septum 12 varies widely within the population. In some people, septum primum 14 extends to and overlaps with septum secundum 16. The septum primum 14 may be quite thin. When the anatomical apertures 18a is present, blood could travel through the anatomical aperture 18a between septum primum 14 and septum secundum 16 (referred to as “the PFO tunnel”). Additionally or alternatively, the presence of an ASD could permit blood to travel through an aperture in the septal tissue, such as through the anatomical aperture 18b.

[0028] In this application, “distal” refers to the direction away from a catheter insertion location and “proximal” refers to the direction nearer the insertion location. Additionally, the term “delivery configuration” refers to the configuration of a device, such as an occluder, when it has a reduced profile in a delivery catheter. The term “deployed configuration” refers to the configuration of the device, such as an occluder, when it has deployed from the catheter, such as at the desired implantation location.

[0029] FIG. 2 illustrates an exemplary occluder with which systems and techniques disclosed herein may be used. An occluder 70, for example, is illustrated as deployed in the septum 12 of a heart. The device operates to close an aperture in the septum by securing the septum in a closed manner. The reference numerals used to identify

components of the described embodiment are disposed on multiple figures where the component is illustrated. The reference numerals are intended to facilitate an overall understanding of the invention and the relationship between components illustrated in different figures.

[0030] The embodiment described in conjunction with FIGS. 5-8 has some similarities to the device disclosed in U.S. Patent Application No. 10/890,784, entitled *Tubular Patent Foramen Ovale (PFO) Closure Device with Locking Mechanism*, filed on July 14, 2004; U.S. Patent Application No. 60/549,741, entitled *Delivery/Recovery System for Clover Leaf Septal Occluder*, filed on March 3, 2004; U.S. Patent Application No. 60/612,857, entitled *Delivery/Recovery Systems for PFO Occluder with Catch System*, filed September 24, 2004; U.S. Patent Application No. 60/663,289, filed March 18, 2005, entitled *Delivery/Recovery System for PFO Occluder with Catch System*; U.S. Patent Application No. 60/662,990, filed March 18, 2004, entitled *Suture Delivery/Recovery System for PFO Occluder with Catch System*; all of which have the same assignee as the present application, and are incorporated herein by reference in their entirety. These incorporated documents describe how a device can be formed by making cuts or slits in a tube and compressing the ends, and how to deliver such a device.

[0031] As shown in FIGS. 5-8, the occluder 70 is formed from a tube (which can be extruded or rolled) that forms distal petals 72 produced by slits 74 in the distal portion of tube according to the cutting pattern shown in FIG. 5. As shown in FIG. 6, the distal portion 20 of the tube includes 8 slits 74 that form 8 extended segments of the tube that form the distal loops or petals 72. As apparent from the figures, the slits extend the entire distance of the distal portion of the tube between central tube 78 and distal end 76 so that the loops of the same cross section are formed. Upon application of force F_d to distal end 76, extended segments defined by slits 74 bow and twist outward to form distal petals 72 in distal side of the occluder 70. The movement of the segments during deployment is such that the segments rotate in an orthogonal plane relative to the axis of the device. Central tube 78 may be constrained during the application of force F_d , or any combination of forces sufficient to reduce the axial length of the tube may be applied. One end of each of distal petals 72 originates from central tube 78, while the other end originates from distal end 76 (FIGS. 6 and 7). Proximal petals 82 may be formed in proximal portion 40, as shown in FIGS. 6-8, making slits 84 between central tube 78 and proximal end 86 using the same cutting pattern described above, and applying force F_p or combination of

forces sufficient to reduce the axial length of the tube, allowing struts 82 to bow and twist outward to form proximal petals 82 in proximal portion 40 of the occluder 70. One end of each of distal petals 82 originates from central tube 78, while the other end originates from proximal end 86.

[0032] The tube(s) forming occluder 70 may be formed from a biocompatible metal or polymer. In at least some embodiments, the occluder 70 is formed of a bioabsorbable polymer, or a shape memory polymer. Shape memory polymers can be advantageous so that the structure of the device assists in pressing the PFO tunnel closed. In other embodiments, the occluder 70 is formed of a biocompatible metal, such as a shape memory alloy (e.g., nitinol). The thermal shape memory and/or superelastic properties of shape memory polymers and alloys permit the occluder 70 to resume and maintain its intended shape in vivo despite being distorted during the delivery process. Alternatively, or additionally, the occluder 70 may be formed of a bioabsorbable metal, such as iron, magnesium, or combinations of these and similar materials. Exemplary bioabsorbable polymers include polyhydroxyalkanoate compositions, for example poly-4-hydroxybutyrate (P4HB) compositions, disclosed in U.S. Patent No. 6,610,764, entitled *Polyhydroxyalkanoate Compositions Having Controlled Degradation Rate* and U.S. Patent No. 6,548,569, entitled *Medical Devices and Applications of Polyhydroxyalkanoate Polymers*, both of which are incorporated by reference in their entirety.

[0033] The cross-sectional shape of tube may be circular or polygonal, for example square, or hexagonal. The slits 74, 84 may be disposed on the face of the polygon (i.e., the flat part) or on the intersection of the faces.

[0034] The tube can be injection molded, extruded, or constructed of a sheet of material and rolled into a tube. The sheet of material could be a single ply sheet or multiple ply. The slits that form the segments could be cut or stamped into the sheet prior to rolling the sheet into a tube to connect the ends to form an enclosed cross section. Various geometrical cross sections are possible including circular, square, hexagonal and octagonal and the joint could be at the vertex or along the flat of a wall if the cross section is of a particular geometry. Various attachment techniques could be used to join the ends of the sheet to form a tube, including welding, heat adhesives, non-heat adhesives and other joining techniques suitable for in-vivo application.

[0035] The petal configuration, illustrated in FIG. 8, is the deployed configuration. The occluder 70 can be secured in the petal configuration by a catch system that holds the ends of the tube together, certain embodiments of which are described below.

[0036] The transformable design of occluder 70 enables occluder 70 to be delivered in a low-profile, delivery configuration, and to be converted readily, i.e., by reducing the axial length, in place to the high-profile, deployed configuration. Moreover, the conversion can readily be effected by forcing distal end 76 and proximal end 86 closer together. For example, distal portion 20 and proximal portion 40 of occluder 70 may be deployed in separate steps, or both distal portion 20 and proximal portion 40 of occluder 70 may be exposed (e.g., out of the delivery catheter) prior to engaging the catch system and deployed together as the catch member is engaged. Use of the terms distal and proximal portions 20 and 40, respectively, include the loops or other geometries and configurations that are formed on the distal and proximal sides, respectively.

[0037] Occluder 70 may be made in any one of several ways. Slits 74 and 84 may be cut such that tube bends into its intended configuration following deployment in vivo. Specifically, slits 74 and 84 may be cut to produce segments 72 and 82 (as illustrated in FIGS. 5, 6) of a thickness that facilitates the bending and formation of loops 72 and 82 (as illustrated in FIGS. 7, 8) upon the application of forces F_d and/or F_p during deployment. The segments 72 and 82 that form the loops are referenced with the same reference numeral. As an alternative, or additionally, a tube formed of a shape memory material may be preformed into its intended configuration ex vivo so that it will recover its preformed shape once deployed in vivo. According to at least some embodiments, this preforming technique produces more reliable deployment and bending of occluder 70 in vivo. An intermediate approach may also be used: tube may be only slightly preformed ex vivo such that it is predisposed to bend into its intended shape in vivo upon application of forces F_d and/or F_p .

[0038] FIG. 2 shows a deployed occluder 70 in a human heart with a catch member 50 engaged (much of the catch member is obscured by the central tube of the occluder). The term "catch system" describes the portion/aspect of the device that secures the device in the deployed configuration, it may be a single piece or a group of connected or assembled pieces. The catch member is the portion of the catch system that engages with

the occluder to hold the occluder in the deployed configuration and is described in more detail below.

[0039] This particular type of occluder 70 and delivery sequences are described for purposes of illustration and explanation; of course, other types of occluders can be deployed using the deployment catch systems described herein. The catch member 50, as illustrated, is disposed in an radially central location in the occluder 70 and is schematically illustrated as a separate piece than the occluder 70. In a preferred embodiment, the catch member may be fixed to one end of the tube that forms occluder 70. For example, a flange 92 may be fixed to the distal end 39 (shown in FIG. 6 and FIG. 10) of the tube.

[0040] In general, references to "occluder 70" herein may be inclusive of catch member 50, depending on the context, for example, unless separately listed or otherwise stated. One end of tube, preferably proximal end 86, is able to move with respect to the catch member 50 (and especially the catch system) so that the distal and proximal petals 72 and 82 can move from the delivery configuration to the deployed configuration. The inside surface of the tube is able to slide over the catch member 50 so that, when the proximal end of the occluder 70 rests against a proximal ridge of catch member 50, the occluder 70 is secured in its deployed configuration. The catch member 50 is included in the catch system that includes a portion for connection to the delivery/recovery system, including, for example, a threaded section illustrated and described in more detail below.

[0041] FIG. 3 illustrates the insertion of an occluder 70 in a human subject 122 using a delivery assembly 124 in accordance with an aspect of the disclosure. A portion of delivery assembly 124, including an occluder 70 and a delivery mechanism for the occluder 70, which can be externally manipulated by a clinician, is inserted into the subject through an incision point 126. The distal end of the delivery assembly is advanced toward and into the heart 10 until the distal end is in proximity to the defect to be closed, as seen in FIG. 4.

[0042] FIG. 9A shows an embodiment 200 for a catch member, that includes a collapsible tip. The catch member 200 includes a cylindrical catch body 201 and a distal flange 202 (which is the same as flange 92 in FIGS. 2 and 6). The catch member 200 includes a proximal ridge 204 disposed on its proximal portion and a slot 206 at its proximal end. The catch member 200 also includes a proximal tip 208, which can be adapted for connection to a portion of the delivery system. For example, it may be

threaded. The distal flange 202 of the catch member 200 engages the distal end 39 of the occluder 70. The proximal ridge 204 of the catch member 200 engages the proximal end 44 of the occluder 70, holding the occluder 70 in its deployed configuration. The proximal tip 208 of the catch member 200 is collapsible; that is, due to slot 206, the diameter of the proximal portion of the catch member 200 can be reduced by compressing the sides of the proximal tip 208. The collapsible proximal tip 208 of the catch member 200 facilitates delivery and deployment of the occluder 70.

[0043] A portion 220 of a delivery assembly 124 is shown in FIG. 9B. During delivery, the collapsible proximal tip 208 of the catch member 200 can be fixed in the compressed configuration by an inner catheter 90 due to the flexibility introduced by the slot 206, for example. This reduced profile enables the proximal ridge 204 of the catch member 200 to slide more easily through the central tube 78 and proximal end 86 of the occluder 70. This means that reduced force typically will be sufficient to force the occluder 70 into the deployed configuration and the device is less likely to be damaged by the deployment process. When the inner catheter 90 is removed, slot 206 is opened and the proximal tip 208 expands back into its original configuration shown in FIG. 9A. When slot 206 is opened and the proximal tip 208 of the catch member is in its original configuration, the diameter of the proximal ridge 204 is greater than the diameter of the catch body 201.

[0044] FIG. 9C is a perspective view of the catch member 200. In an exemplary embodiment of catch member 200, catch body 201 has a length of about 0.6 inch and a diameter of about 0.065 inch. The proximal ridge 204 has a length of about 0.04 inch and a diameter of about 0.075 inch. The proximal tip 208 has a length of about 0.05 inches past the proximal ridge 204 and a diameter of about 0.070 inch, slightly larger than the diameter of the catch body 201. It is understood that the diameter of the proximal tip 208 can also be the same as the diameter of the catch body 201. The slot 206 has a length of about 0.25 inches and a width of about 0.020 inches. The distal flange 202 has a diameter of about 0.08 inch. In another embodiment of the catch member 200, the catch body 201 has a length of about 1.2 inch and a diameter of about 0.058 inch. The proximal ridge 204 portion has a length of about 0.02 inch and a normal diameter of about 0.08 inch. The proximal tip 208 has a length of about 0.18 inch past the proximal ridge 204 and a normal diameter of about 0.070 inch, slightly larger than the diameter of the catch body

201. The slot 206 has a length of about 0.300 inches and a width of about 0.020 inch. These dimensions are approximate and provided by way of example only.

[0045] In certain embodiments, it is desirable for the catch body 201 of the catch member 200 to have some interference with the inner portion of the occluder 70 as the occluder 70 slides over the catch member 200 into the deployed configuration. The interference is provided by dimensioning the catch body 201 so that the catch body 201 has a diameter close to an inner diameter of the occluder 70, particularly an inner diameter of the proximal portion of the occluder 70, even while the proximal tip 208 of the catch member 200 is in its compressed position. This friction will provide a temporary catch mechanism, which will tend to “stick” the occluder 70 in a partially deployed configuration before the catch member 200 is fully activated.

[0046] FIG. 10A illustrates another embodiment of a catch member 250. This catch member 250 also provides a “temporary” catch for the device that holds the occluder 70 in its partially deployed configuration during the deployment process before the catching mechanism is completely secured. Catch member 250 includes a distal flange 252, a catch body 254, a proximal tip 258, and a proximal ridge 256. The relative diameter of the proximal ridge 256 to the proximal tip 258 may be smaller than illustrated in FIG. 10A. The basic function of catch member 250 is similar to the function of catch member 50 and catch member 200. As shown in FIG. 10B, which illustrates an occluder assembly 300 including an occluder 70 and catch member 250, when the occluder 70 is deployed, the catch member 250 maintains the occluder 70 in a reduced axial length position, its deployed configuration. FIG. 10 is a schematic illustration and shows the proximal ridge 256 having an exaggerated diameter. The distal flange 252 and proximal ridge 256 of the catch member 250 provide interference fits with respective ends of the occluder 70 and keep the occluder 70 in its deployed configuration. The catch body 254 of this catch member 250 has a tapered or graduated cylindrical profile, composed of two sections having two different diameters. A distal section 259 has a first diameter D_1 and a proximal section 257 has a second diameter D_2 . The distal section 259 and the proximal section 257 are joined by a sloped section 260.

[0047] In certain embodiments, the first diameter D_1 of the distal section 259 of the catch body 254 is greater than the second diameter D_2 of the proximal section 257 of the catch body 254. The sloped section 260 can have a shallow or a steep slope. The occluder 70 is formed of a tubular element that defines one or more inner diameters. In

certain embodiments, the difference in the first and second diameters D_1 and D_2 corresponds to a similar difference in the inner diameters of respective portions of the occluder 70. For example, in some embodiments, the distal end 76 and distal portion 20 of the occluder 70 have an inner diameter that is similar to the first diameter D_1 of the distal section 259 of the catch body 254. The central tube 78, proximal portion 40 and proximal end 86 of the occluder 70 have an inner diameter similar to the second diameter D_2 of the proximal section 257 of the catch body 254. During deployment, the distal portion 20 and central tube 78 of the occluder 70 ride over the catch body 254. Due to similarity in diameter dimensions, the interference between the distal portion 20, central tube 78 of the occluder 70 and the distal section 259 of the catch body 254 allows the distal portion 20 of the occluder 70 to be temporarily caught at the partial deployed configuration, and therefore provide operator with full control of the deployment process. The proximal portion 40 can only travel over the proximal section 257 of the catch member 250 until the proximal portion 40 reaches the sloped section 260 of the catch body 254 and is blocked by the gradient between the first diameter D_1 and the second diameter D_2 . The proximal portion 40 of the occluder 70 then gets wedged behind the proximal ridge 256 of the catch member 250 and thereby catches the occluder 70 in its deployed configuration. Similarly, the interference between the proximal portion 40 of the occluder 70 and the proximal section 257 of the catch member 250 allows the proximal portion 40 of the occluder 70 to be temporarily caught in partially deployed configuration. According to an alternative embodiment, the distal portion 20 and central tube 78 of the occluder 70 ride smoothly over the distal section of the catch body 254, while the proximal section 40 of the occluder 70 interferes with the proximal section 257 of the catch member 250, thereby providing a partial catch.

[0048] According to an alternative embodiment, the inner diameter of the entire length of the occluder 70 is similar to the second diameter of the distal section 259 of the catch body 254. The distal portion 20, central tube 78, and proximal portion 40 of the occluder 70 ride over the catch body 254. Similarly, the interference between the distal portion 20, central tube 78, proximal portion 40 of the occluder 70 and the distal section 259 of the catch body, allows the occluder 70 to be temporarily caught during the deployment process. In preferred embodiments, this feature is combined with the compressible proximal tip 258 described above. By this mechanism, the occluder 70 can

be held in place while the compressible proximal tip 258 is still secured to the delivery system and before it is expanded into its final deployment position.

[0049] FIGS. 10C and 10D provide more detailed cross-sectional views of portions 300 and 310 of the occluder 70 and catch member assembly 300, and of the interaction between the inner portion of the occluder 70 and the catch member 250.

[0050] The embodiment illustrated in FIGS 10A-10C is particularly useful to provide a temporary catch mechanism that enables the occluder to remain in a partially deployed configuration when the occluder is held in a fixed position with respect to the catch member by the interference fit between the catch member and the occluder.

[0051] The embodiments and techniques described here are described preferably for use with a device made of a polymer and formed from a single tube, such that the tube is a single monolithic material. The catch mechanism can be all or partly monolithic or integral with the tubular structure, or there can be an absence of any type of bonding or rigid connection to the rest of the tubular structure, in which case there may be some spring force or other force that holds the catch mechanism in place. While the device is thus shown as being substantially formed from a single tubular body, the catch mechanism as described in the embodiments above could be used with other types of devices, including those formed from many pieces, and including devices formed from other materials, including stainless steel or Nitinol.

[0052] In cases in which the device is made of a polymer, it can be desirable to add an additive or coating to the material to make it radiopaque to make it more visible in a wider variety of imaging techniques.

[0053] While a compressible tip for a catch member has been described as having a single slot, it will be appreciated that a compressible tip could be implemented using other techniques, for example, by providing multiple slots.

[0054] It will be appreciated that while a particular sequence of steps has been shown and described for purposes of explanation, the sequence may be varied in certain respects, while still obtaining the desired deployment or in some cases to effect deployment in a particular way. For example, the delivery sheath may be advanced or retracted at varying times and in varying degrees, the proximal and distal portions of the occluder may be deployed into the looped configuration in a different sequence, etc.

[0055] Having described many embodiments, it should be apparent that modifications can be made without departing from the scope of the present invention.

CLAIMS

Claims:

1. A collapsible medical device for occluding an aperture in a body, the medical device having a first configuration as a reduced profile and a second configuration as an expanded profile, the medical device being adapted to be delivered through a delivery system into a desired delivery location, the medical device comprising:
 - a proximal side and a distal side;
 - an occluder portion movable between first and second configuration; and,
 - a catch system for holding the medical device in the second configuration including a catch member with at least two compressible prongs at the proximal end and a bump on the surface of the catch member for at the proximal end such that during deployment, the proximal end of the catch member is adapted to pass through an inner passageway of the occluder while the compressible prongs are held in a compressed position and the catch member is adapted to secure the device in the deployed configuration when the compressed portion is unconstrained.
2. The medical device recited in claim 1, wherein the catch member is made of polymeric material.
3. The medical device recited in claim 2, wherein the bump on the surface is disposed at a location close to the prongs.
4. The medical device recited in claim 1, wherein the prongs extend more than one third of the distance of the catch member.
5. The medical device recited in claim 1, wherein the bumps on the catch member prongs have a stepped profile above the surface of the catch member.

6. The medical device recited in claim 5, wherein the space between the prongs is about one third of the diameter of the catch member.
7. The medical device recited in claim 1, wherein the body of the catch member is so dimensioned that the catch body and the occluder have a friction fit.
8. A collapsible medical device for occluding an aperture in a body, the medical device having a first configuration as a reduced profile and a second configuration as an expanded profile, the medical device being adapted to be delivered through a delivery system into a desired delivery location, the medical device comprising:
 - an occluder portion that is adapted to move from a reduced profile to an expanded profile, the occluder portion including an axial passage along the length of the occluder,
 - a catch member adapted to be disposed in the passage such that the occluder can move from the reduced profile configuration to the expanded profile configuration with the catch member in the passageway,
 - a catch system including an axially deformable section of the catch member so that the catch member having at least two diameters, a first diameter at a proximal location and a second, larger, diameter at a distal location, wherein the occluder has an inner passageway that is configured to be a diameter larger than the first diameter and smaller than the second diameter.
9. The collapsible medical device recited in claim 8, wherein the second diameter and the passageway have a friction fit.
10. A collapsible medical device for occluding an aperture in a body, the medical device having a first configuration as a reduced profile and a second configuration as an expanded profile, the medical device being adapted to be delivered through a delivery system into a desired delivery location, the medical device comprising:

an occluder portion that is adapted to move from a reduced profile to an expanded profile, the occluder portion including an axial passage along the length of the occluder,

a catch member adapted to be disposed in the passage such that the occluder can move from the reduced profile configuration to the expanded profile configuration with the catch member in the passage way,

a catch system including an axially deformable section of the catch member so that the catch is configured to have a diameter slightly larger than a portion of the tube that forms the occluder such that when the occluder tube is moved axially with respect to the catch member there is an interference fit at an intermediate stage of deployment that forms a temporary catch.

11. The medical device recited in claim 10, wherein the catch member is made of polymeric material.
12. The medical device recited in claim 10, wherein the catch member includes a bump on the proximal portion.
13. The medical device recited in claim 12, wherein the bump on the catch member prongs has a stepped profile above the surface of the catch member.
14. The medical device recited in claim 12, wherein the catch member includes an axial slit along about one third of the distance of the catch member.
15. The medical device recited in claim 14, wherein the axial slit is about one third of the diameter of the catch member.

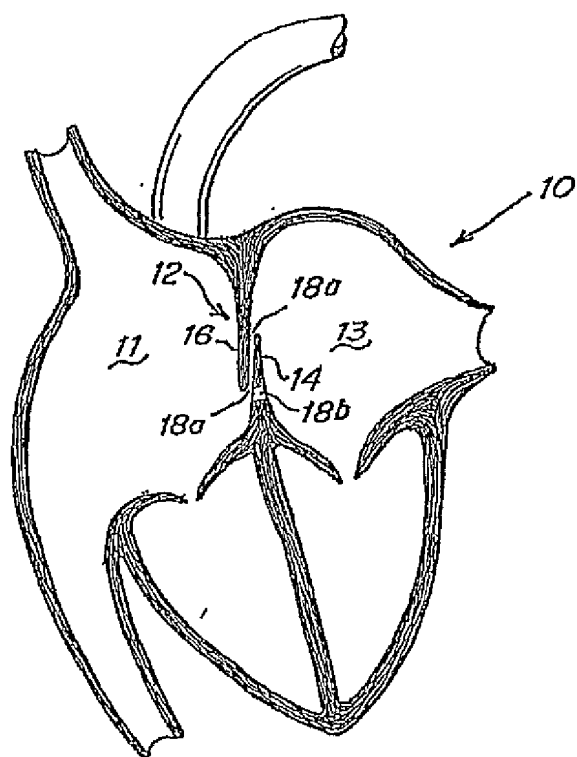


Fig. 1

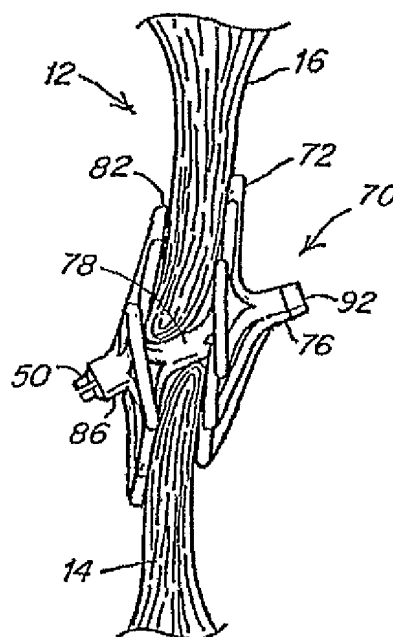
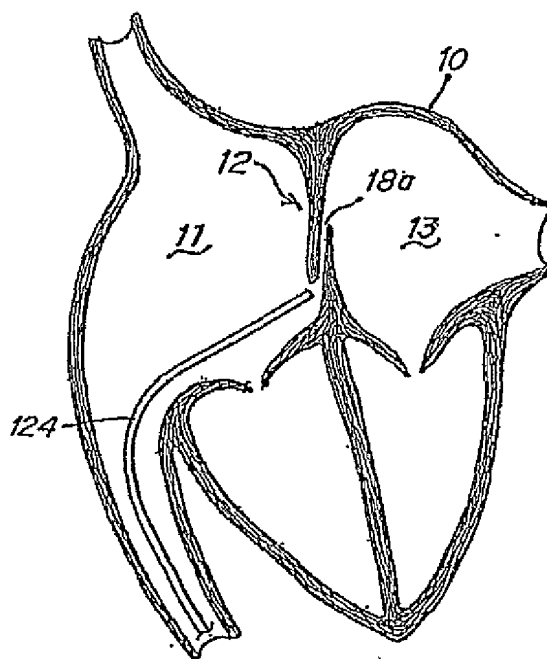
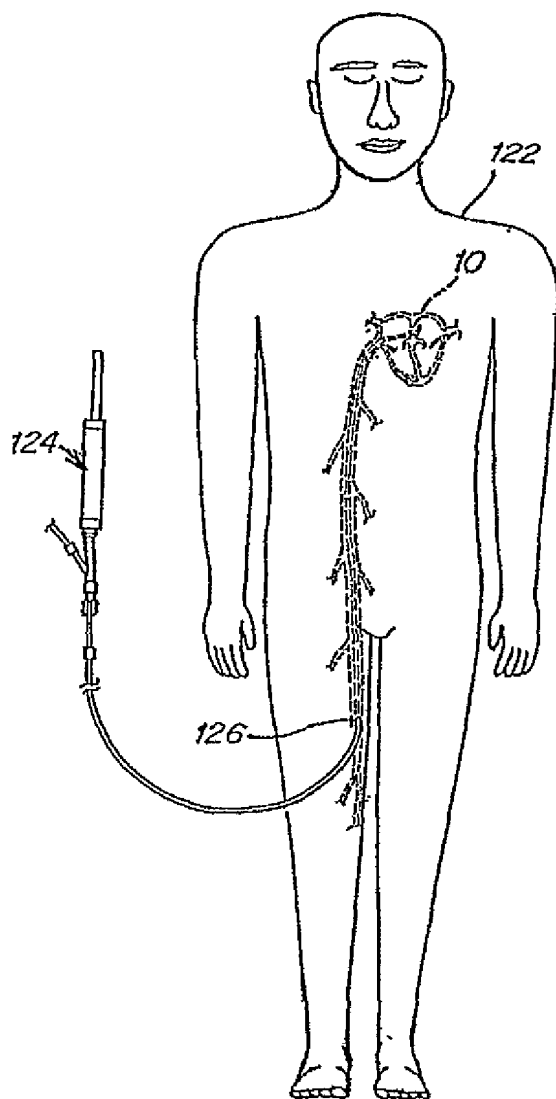
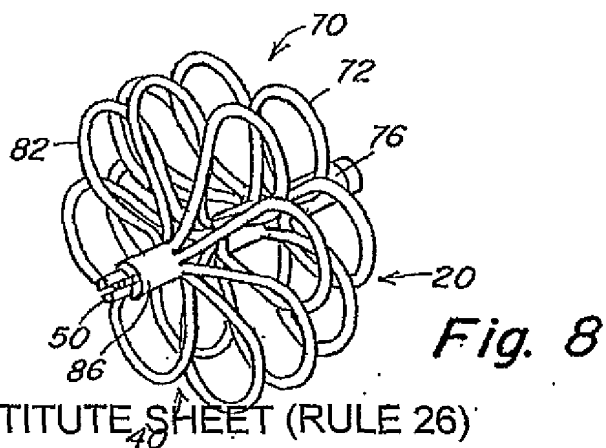
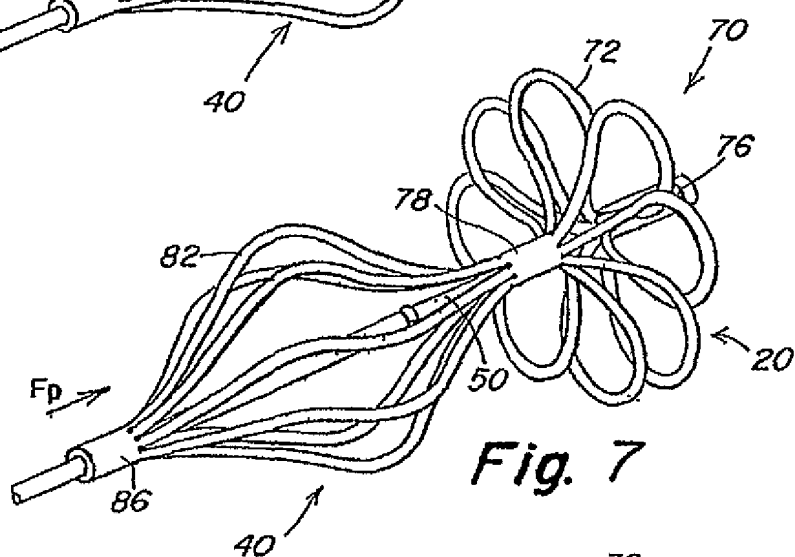
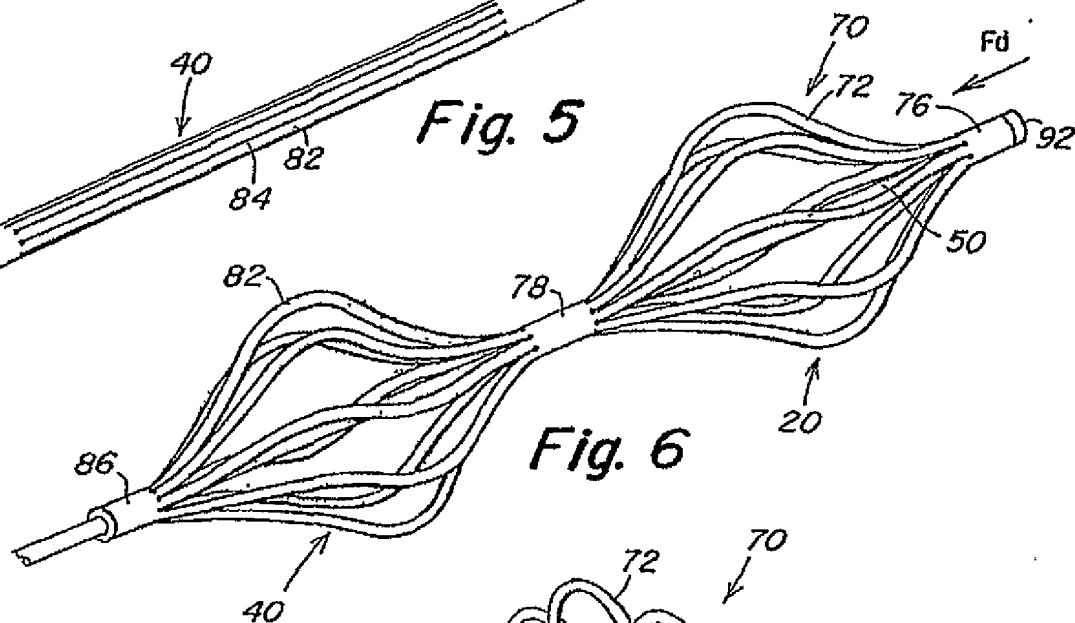
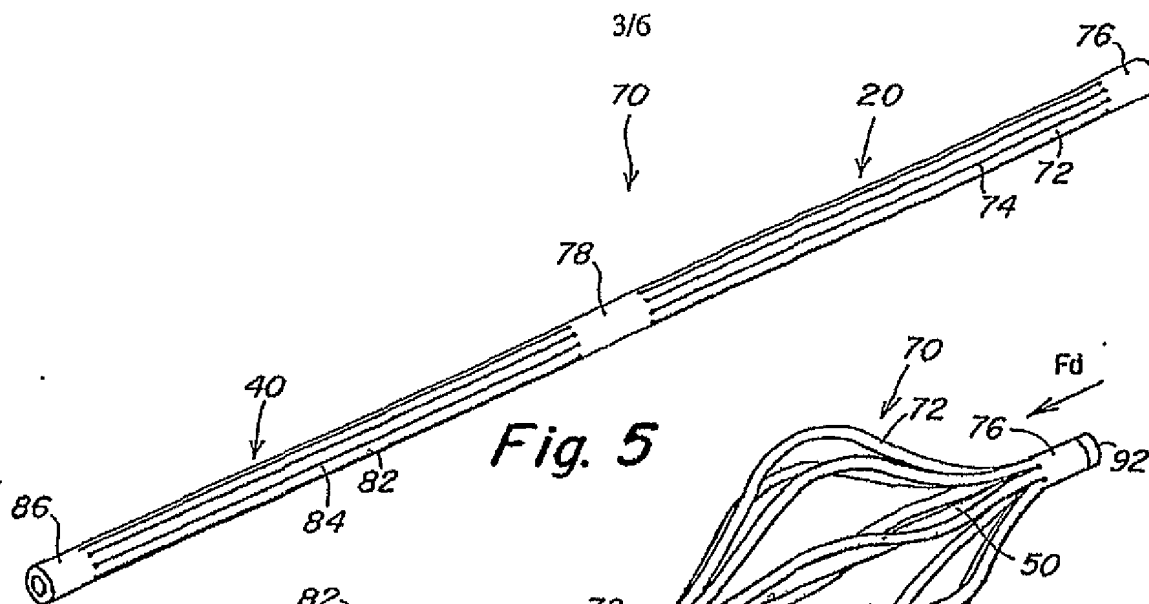
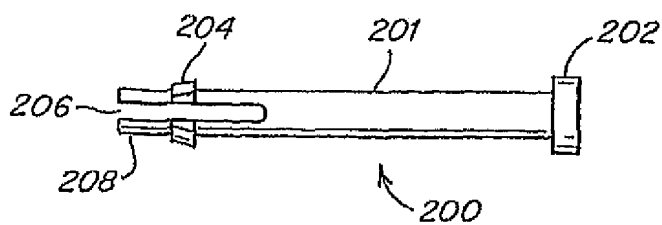
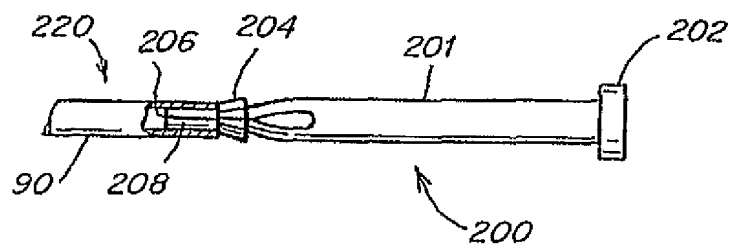
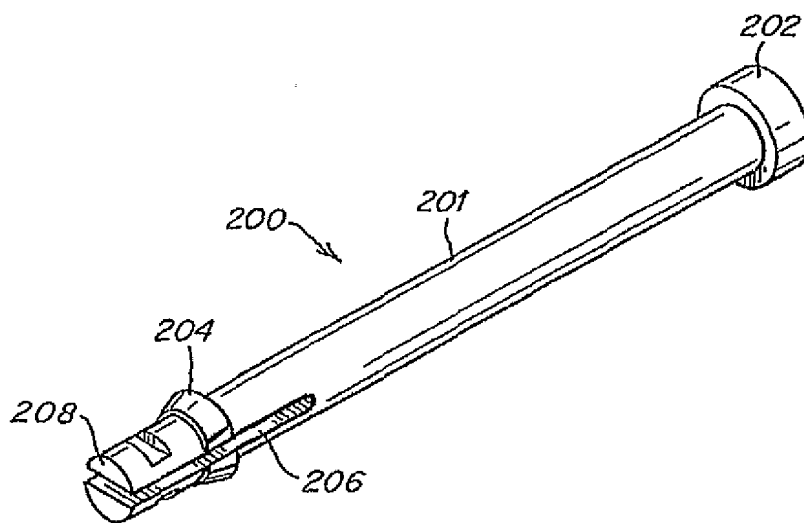


Fig. 2

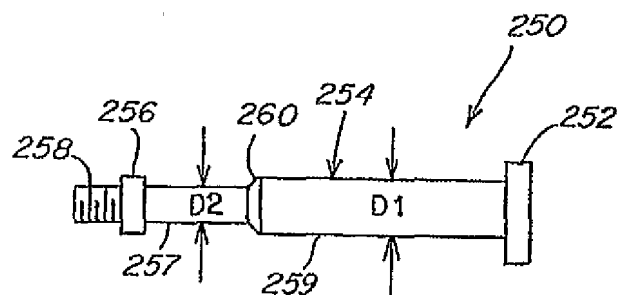
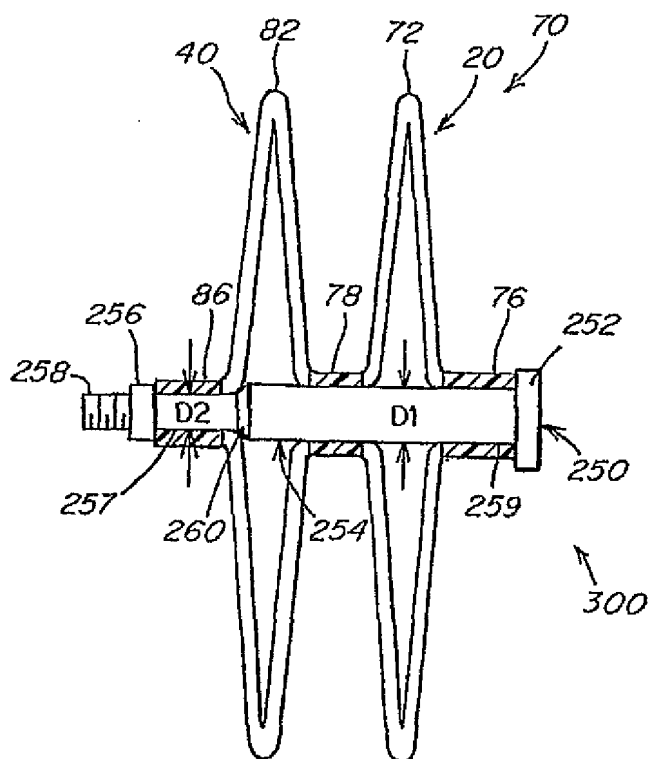




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*Fig. 9A**Fig. 9B**Fig. 9C*

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*Fig. 10A**Fig. 10B*

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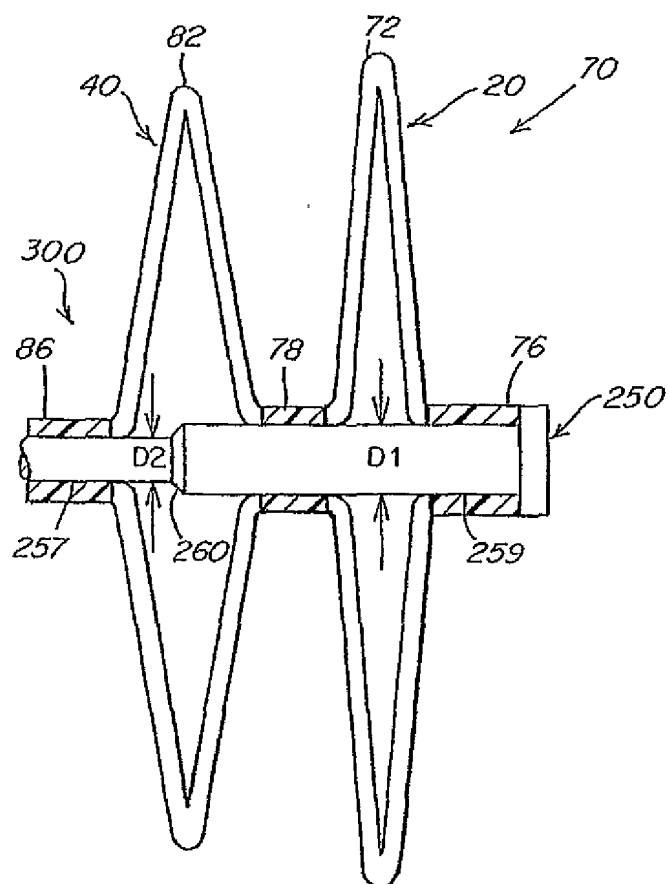


Fig. 10C

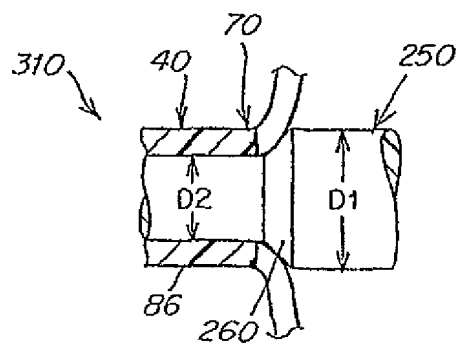


Fig. 10D
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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/009978

A. CLASSIFICATION OF SUBJECT MATTER
ADD. A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/006990 A (NMT MEDICAL, INC; CHANDUSZKO, ANDRZEJ, J) 27 January 2005 (2005-01-27) paragraph [0066]	1-15
L,P, X	WO 2005/110240 A (NMT MEDICAL, INC; CHANDUSZKO, ANDRZEJ, J; WIDOMSKI, DAVID, R; DEVELLIA) 24 November 2005 (2005-11-24) paragraph [0042]	1-15
X	US 6 312 446 B1 (HUEBSCH JOSEPH ET AL) 6 November 2001 (2001-11-06) column 6, line 66 - column 7, line 20	1-15



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

5 July 2006

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/009978

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2005006990	A	27-01-2005	CA EP	2532112 A1 1651116 A2
				27-01-2005 03-05-2006
WO 2005110240	A	24-11-2005	NONE	
US 6312446	B1	06-11-2001	NONE	